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| EXAMINER |
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SNOW, BRUCE EDWARD

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 01/07/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,844

Applicant(s)

MICHELSON, GARY K. *OK*

Examiner

Bruce E Snow

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 131,133,135,137-145,205,206 and 213-215 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,5,19-42,44-56 and 259-271 is/are allowed.
- 6) ☒ Claim(s) 43,219,228-255 and 277-284 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/9/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Continuation of Disposition of Claims: Claims pending in the application are 1,3,5,19-56,131,133,135,137-145,203-209,213-215,228-255 and 258-284.

DETAILED ACTION

In response to this office action, the Examiner requests all new proposed drawings and drawing limitations submitted in Amendment D and hereafter are resubmitted and shown in red.

Election/Restrictions

Claims 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276 (all claims depending from 131) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Regarding claim 131, the elected embodiment shown in figures 12-15 has left and right facets that are identical, the left facet is not steeper than the right facet. Further note that the last line added to the claim, "*said first and second surface projections having at least one facet with the perimeter..*" is not understood.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

Applicant's arguments filed 10/9/03 have been fully considered but they are not persuasive.

Regarding the rejection of claim 219 in view Aebi et al, applicant states that all facets have included angles of 90 degrees or less which is not persuasive because claim 219 fails to specify how the angles are being measured; are the facet angles

being measured from the front, back, etc? All claim limitations are given their broadest interpretation. It is the Examiner's instinct to measure the rearward facet of Aebi et al from the rear relative the base producing an angle greater than 90 degrees.

Specification

The amendment filed 10/9/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The following proposed drawings and associated descriptions added to the specification is considered new matter.

Figures 1A and 1B are new matter. These figures show a completely new spinal implant embodiment in which one having ordinary skill in the art reading the original claims (of 09/457,228) would not have conceived. It is noted that the embodiment was incorporated from U.S. Patent No. 5,593,409, however that drawing does not show the current projections. The combination of the current invention surface projections and previous embodiment is new matter. Note that proposed Figure 1A shows the surface projects at an angle relative the leading and trailing ends which is new matter.

Figure 1C is new matter. Original claim 45 says nothing about a motion preserving device. It is unclear what a motion preserving device is.

Figure 12A and 12B, what is the difference?

Figure 14A and 14B – it is mechanically impossible to have anything but a V-shape. Please confirm that claim 18 is original to 09/457,228.

Applicant is required to cancel the new matter in the reply to this Office Action.

Note that proposed drawing 14C is approved by the Examiner.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, all claims must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Due to the large number of claims only some specific claims will be addressed as examples purposes only. ***It is Applicant's responsibility to ensure all claimed limitations are shown in the drawings or to remove limitations or cancel the claims of the limitations not shown.***

Examples of claims not shown: Claim 21 – arcuate upper and lower surfaces; claim 22-24, Claim 47 – “cap”; 228-232, 269.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 43, 247, and repeats thereof, what is and how is the fusion implant a "motion preserving device"? Please cancel this claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 219, 228-255, 277-284 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al (6,482,233).

Aebi et al teaches a spinal implant comprising bone engaging structures that are generally pyramid-shaped formed on the upper and lower surfaces of the implant. The engaging structures are slanted towards the anterior therefore having a forward

(anterior) facing facet that is shorter than a rearward facing facet and said forward facing facet has a steeper slope; the structures further include side facets. Applicant claims the opposite Aebi et al claiming the bone engaging structures slant rearward (posteriorly). However, both Aebi et al and applicant teach the bone engaging structures slant in a direction such to allow ease of insertion and to avoid retropulsion. See Aebi et al column 4, lines 30-34 and applicant's specification page 5, lines 5-9 and lines 15-19. It would have been obvious to one having ordinary skill in the art to have slanted the bone engaging structures of Aebi et al posteriorly such that the implant could be introduced posterior-laterally and/or resist movement in the direction towards the spinal cord when a surgeon deems it necessary. Note that Aebi et al teaches the steeper angled face can be "from about 0 to 30 degrees" which the Examiner interprets to include negative angles.

Many of applicant's dependent claims claim a wide range of possibilities, for example, an angle can be less than 90 degrees, perpendicular, or greater than 90 degrees; the groove can be v-shaped, u-shaped, box-like shape; etc, lacking any criticality in the specification, the use of any claimed variation, range, or configuration in lieu of those used in the references solves no stated problem and produces no benefits and would have been an obvious matter of design choice for someone skilled in the art.

Additionally, many of the dependent claims claim elements/materials/shapes/tools/etc. which are taught by the reference or are well known in the prosthetic art and would have been obvious to one having ordinary skill.

Claims 219, 228-255, 277-284 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Paul et al (6,258,125).

Paul et al teaches a spinal implant comprising a plurality of surface projections on upper and lower surfaces. Said projections having a forward facet, rearward facet, and two side facets; wherein the forward facet is longer and rearward facet has a steeper slope and an angle greater than 90 degrees. See figures 9 and 10A which are interpreted as having said four facets.

In the alternative, under 35 U.S.C. 103(a): Many of applicant's dependent claims claim a wide range of possibilities, for example, an angle can be less than 90 degrees, perpendicular, or greater than 90 degrees; the groove can be v-shaped, u-shaped, box-like shape; etc, lacking any criticality in the specification, the use of any claimed variation, range, or configuration in lieu of those used in the references solves no stated problem and produces no benefits and would have been an obvious matter of design choice for someone skilled in the art.

Additionally, many of the dependent claims claim elements/materials/shapes/tools/etc. which are taught by the reference or are well known in the prosthetic art and would have been obvious to one having ordinary skill.

Claims 219, 228-255, 277-284 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fraser (6,432,106).

Fraser teaches a spinal implant comprising a plurality of surface projections on upper and lower surfaces. Referring to all figures, specifically figure 10, said projections having a forward facet, rearward facet, and two side facets; wherein the forward facet is longer and rearward facet is undercut and has a steeper slope and an angle greater than 90 degrees.

In the alternative, under 35 U.S.C. 103(a): Many of applicant's dependent claims claim a wide range of possibilities, for example, an angle can be less than 90 degrees, perpendicular, or greater than 90 degrees; the groove can be v-shaped, u-shaped, box-like shape; etc, lacking any criticality in the specification, the use of any claimed variation, range, or configuration in lieu of those used in the references solves no stated problem and produces no benefits and would have been an obvious matter of design choice for someone skilled in the art.

Additionally, many of the dependent claims claim elements/materials/shapes/tools/etc. which are taught by the reference or are well known in the prosthetic art and would have been obvious to one having ordinary skill.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within


TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

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BRUCE SNOW
PRIMARY EXAMINER